

**REMARKS****Claim Rejections – 35 U.S.C. § 102**

Claims 4, 5, 6 and 22 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Greenwood (US 5,120,314). Regarding claim 4, the Examiner states that Greenwood discloses an I.V. flush syringe assembly comprising a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface further including a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the contact area is the area 50 at the distal end of the barrel), a plunger (30) including an elongate body portion (32) having a proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1), wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the barrel at area 50 has a portion with multiple tabs such as 67 in Fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction). The tabs engage with the

plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid), wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall).

Applicants respectfully traverse this basis for rejection.

It has long been the law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaa Bros. v. Union Oil Co. of California*, 814 F.2d 638, 631 (Fed. Cir. 1987). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But

disclosure of each element is not quite enough – this court has long held that '[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.*'") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original)).

Claim 4 (and thus claims 5, 6 and 22 dependent therefrom) is directed to an I.V. flush syringe assembly comprising, *inter alia*, a barrel having an inside surface defining a chamber for retaining fluid, the inside surface including a contact area at the distal end of the barrel which has a higher coefficient of friction than the inside surface of the barrel outside of the contact area for frictionally engaging the stopper and holding it in a partially deflected position to prevent reflux of fluid after the fluid has been delivered from the chamber. In this way, the contact area restrains the compressed stopper from moving in the proximal direction without any need for mechanical interference. *See, e.g.*, Figure 9. In the preferred embodiments recited in claims 5 and 6, the contact area includes a plurality of annular deformations, which can be annular projections on the inside surface of the barrel. *See, e.g.*, Figure 8.

The Examiner asserts that the single use syringe disclosed in Greenwood has a barrel contact area 50 having a higher coefficient of friction than the barrel surface outside of the contact area for frictionally engaging the stopper when said stopper is in contact with the distal wall of said barrel for frictionally holding the stopper in a partially deflected position. According to the Examiner, tab 67 in Figure 6 and tab 82 in Figure 10 of Greenwood constitute contact areas on the inner surface of the barrel having a higher coefficient of friction than the remainder of the barrel. However, even if true, the instant claims require that the barrel has an inside surface defining a chamber for retaining fluid,

the inside surface including a contact area. In contrast, tabs 67 and 82 in Greenwood are not included as part of the barrel, but rather are part of metal annulus 60 and 80, respectively. According to Greenwood, annulus 60 and 80 are bonded to in place of the syringe barrel. *See* col. 6, lines 19-22; col. 7, line 14. Clearly, a barrel having an inside surface to which an annulus is bonded is not the same thing as a barrel having an inside surface including a contact area.

Thus, even if the annulus in Greenwood has a coefficient of friction greater than the inside surface of the barrel, the Examiner has failed to make out a case of *prima facie* obviousness because the claimed syringe requires the inside surface of the barrel itself have areas of differing coefficients of friction. The Examiner has failed to provide any evidence that so-called "contact area" 50 on the inside surface of the barrel in Greenwood has a higher coefficient of friction than the remaining portions of syringe bore 14. *See Robertson*, 169 F.3d at 745 (citations omitted) ("To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"). Indeed, the need for an annulus to lock the plunger following delivery suggests just the opposite. As such, Greenwood fails to disclose each and every element of the I.V. flush syringe recited in claim 4. *See Verdegaaal*, 814 F.2d at 631.

Claims 4 and 5 specify that the contact area of the inner surface of the barrel includes a plurality of annular deformations, and that the annular deformations are

annular projections. According to the Examiner, the areas above and below ring portion 64 of annulus 60 in Figure 6 of Greenwood constitute two annular projections. However, as explained above, annulus 60 is not part of the inner surface syringe barrel itself, but rather is bonded to the barrel. The areas above and below annulus 60 are locking tabs 62 which are attached to annulus 60. Thus, even if considered annular projections, the locking tabs cannot be considered as included in the claimed "contact area" of the inner barrel surface, as that term is properly construed. *See Verdegaal*, 814 F.2d at 631.

Accordingly, Applicants submit that the Examiner has failed to make out a prima facie case of anticipation of claims 4, 5, 6 and 22 by Greenwood, and reconsideration of this basis for rejection is respectfully requested.

**Claim Rejections – 35 U.S.C. § 103**

a. Claims 18-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Greenwood in view of Lynn (US 5,522,804). According to the Examiner, Greenwood discloses the device substantially as claimed except for a tip cap and flush, but states that Lynn, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better described by Col. 14, lines 20-30). Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution.

Applicants respectfully traverse this basis for rejection.

Claims 18-20 depend from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). As discussed above with respect to the rejection of claim 4, Greenwood does not disclose a syringe barrel having an inside surface defining a chamber for retaining fluid, the inside surface including a contact area at the distal end of the barrel which has a higher coefficient of friction than the inside surface of the barrel outside of the contact area. Furthermore, the Examiner has pointed to nothing in Lynn that remedies the deficiencies of Greenwood in this respect. As such, the combination of Lynn with Greenwood cannot render the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, Applicants submit that the Examiner has failed to make out a *prima facie* case of obviousness of claims 18-20 over Greenwood in view of Lynn, and reconsideration of this basis for rejection is respectfully requested.

b. Claim 21 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Greenwood in view of Ranford (US 5,106,372). According to the Examiner, Greenwood discloses the device substantially as claimed except for a removable needle assembly, but states that Ranford, discloses a similar device wherein the needle assembly is removable. Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with the removable needle assembly, as taught by Ranford, in order to provide a syringe with interchangeable parts which makes it more marketable.

Applicants respectfully traverse this basis for rejection.

Claim 21 depends from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to the rejection of claim 4, Greenwood does not disclose a syringe barrel having an inside surface defining a chamber for retaining fluid, the inside surface including a contact area at the distal end of the barrel which has a higher coefficient of friction than the inside surface of the barrel outside of the contact area. Furthermore, the Examiner has pointed to nothing in Ranford that remedies the deficiencies of Greenwood in this respect. As such, the combination of Ranford with Greenwood cannot render the claimed invention obvious. *See Rijckaert*, 9 F.3d at 1533.

Accordingly, Applicants submit that the Examiner has failed to make out a *prima facie* case of obviousness of claim 21 over Greenwood in view of Ranford, and reconsideration of this basis for rejection is respectfully requested.

**CONCLUSION**

It is believed that claims 4-6 and 18-22 are now in condition for allowance, early notice of which would be appreciated. If any additional fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 02-1666. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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